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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,811	07/11/2005	Bruce J. Gantz	COCH-0129-US1	3607
22506 7590 02/07/2007 JAGTIANI + GUTTAG 10363-A DEMOCRACY LANE FAIRFAX, VA 22030			EXAMINER WU, EUGENE TONG	
			ART UNIT	PAPER NUMBER
			3766	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/518,811	Applicant(s) GANTZ ET AL.	
	Examiner Eugene T. Wu	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 27-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/22/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-26, drawn to an implantable electrode array.

Group II, claims 27-32, drawn to an implantable component of a cochlear implant system.

Group III, claims 33-35, drawn to a method of operating a cochlear implant system.

2. The inventions listed as Groups I, II, and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- a. Claims 1-26 are directed to "an implantable electrode array" including the following features:

- (i) an elongate carrier having a proximal end and a distal end,
- (ii) a plurality of electrodes supported by the carrier,
- (iii) a stabilising or anchoring means extending outwardly from the elongate carrier, and
- (iv) the collar means having an abutment surface to abut at least a portion of the surface of the cochlea and prevent movement of the carrier following insertion of the array into the cochlea.

It is considered that "stabilising collar means having an abutment surface to prevent movement of the carrier following insertion of the array into the cochlea" comprises a first "special technical feature."

- b. Claims 27-32 are directed to "an implantable component of a cochlear implant system" including the following features:

- (i) a housing for a stimulator unit,
- (ii) a first elongate electrode assembly,

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- (iii) a second elongate electrode assembly, and
- (iv) wherein only one of the first and second electrode assemblies is insertable into cochlea at any particular time.

It is considered that "only one of the first and the second electrode assemblies is insertable onto the cochlea at any particular time" comprises a second "special technical feature".

c. Claims 33-35 are directed to "a method of operating a cochlear implant system" including the following features:

- (i) a housing for a stimulator unit,
- (ii) an elongate electrode assembly,
- (iii) the assembly having a proximal end and a distal end and comprising of a plurality of electrodes,
- (iv) one or more of the electrodes closer to the proximal end being adapted to provide stimulation to the basilar region of the cochlea,
- (v) one and more of the electrodes relatively closer to the distal end being adapted to provide stimulation to a location beyond the first basal turn of the cochlea, and
- (vi) when recipient is unable to hear relatively high frequency sounds only activating those one or more electrodes adapted to provide stimulation to the basilar region of the cochlea.

It is considered that "one or more of the electrodes closer to the proximal end being adapted to provide stimulation to the basilar region of the cochlea and one and more of the electrodes relatively closer to the distal end being adapted to provide stimulation to a location beyond the first basal turn of the cochlea and activating those one or more electrodes" comprises a third "special technical feature".

Since the above mentioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the 371 national stage application does not relate to one invention or to a single inventive concept, a priori.

3. During a telephone conversation with Michael Verga on 01/30/2007 a provisional election was made without traverse to prosecute the invention of Group I, implantable electrode array, claims 1-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-35 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

5. The disclosure is objected to because of the following informalities:

- a. Page 2, line 27: "cochlear" should be "cochlea".
- b. Page 8, lines 14-23: All mentions of "facia" should be "fascia".
- c. Page 20, line 7: "cochlear" should be "cochlea".

Appropriate correction is required.

Claim Objections

6. Claims 23 and 24 objected to because "facia washer" should be "fascia washer".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-10, 16, 17, 25, and 26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding these claims, the phrase "and/or" renders the claim indefinite because it is unclear whether the limitations preceding and following the phrase are both part of the claimed invention.

See MPEP § 2173.05.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. In light of the 112 rejections above, the Office is interpreting "and/or" to mean "or".

11. Claims 1-8, 13-15, 20-22, 25, and 26 rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma et al. (WO 00/69513).

Regarding claim 1, Kuzma discloses the same invention substantially as claimed, including an elongate carrier 12 (Figure 1A, 1B) having a proximal end 18, distal end 13, and plurality of electrodes 14, and a stabilizing collar means 18 having an abutment surface 19 (see also Figure 2).

Regarding claim 2, Kuzma discloses the collar means comprising a greater diameter than the remainder of the carrier (Figure 1A).

Regarding claim 3, Kuzma discloses the distal end of the collar means 19 comprising the abutment surface (Figure 1A).

Regarding claim 4, Kuzma discloses the abutment surface extending at substantially a right angle to the carrier (Figure 1A).

Regarding claim 5, Kuzma discloses the collar means 18 positioned at the proximal end 18 (Figure 1A).

Regarding claim 6, Kuzma discloses the collar means formed integrally with the carrier member (Figure 1A).

Regarding claim 7, Kuzma discloses anchoring means 16 (Figure 1A, 2).

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Regarding claim 8, Kuzma discloses the anchoring means extending adjacent the abutment surface (Figure 1A).

Regarding claim 13, Kuzma discloses the electrode array being insertable to a depth at the first basal turn of the cochlea (Figure 2).

Regarding claim 14, Kuzma discloses the electrode array being insertable to a depth just beyond the first basal turn of the cochlea (Figure 5).

Regarding claim 15, Kuzma discloses the same invention substantially as claimed, including an elongate carrier 12 (Figure 1A, 1B) having a proximal end 18, distal end 13, and plurality of electrodes 14, and an anchoring means 16 (see also Figure 2).

Regarding claim 20, Kuzma discloses the electrode array being insertable to a depth at the first basal turn of the cochlea (Figure 2).

Regarding claim 21, Kuzma discloses the electrode array being insertable to a depth just beyond the first basal turn of the cochlea (Figure 5).

Regarding claim 22, Kuzma discloses forming an opening into the cochlea (Page 8, lines 11-13; Figure 2), inserting the electrode array (Page 8, lines 13-21), and abutting a collar means (Page 8, lines 16-21, 23-24).

Regarding claim 25, Kuzma further discloses attaching anchoring means to tissue (Page 8, lines 21-24).

Regarding claim 26, Kuzma discloses forming an opening into the cochlea (Page 8, lines 11-13; Figure 2), inserting the electrode array (Page 8, lines 13-21), and attaching an anchoring means to the tissue (Page 8, lines 21-24).

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12. Claims 1 and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma (US 6,070,105).

Regarding claim 1, Kuzma discloses the same invention substantially as claimed, including an elongate carrier 104 (Figure 1A) having a proximal end 108, distal end 106, and plurality of electrodes 102, and a stabilizing collar 114 having an abutment surface.

Regarding claim 11, Kuzma discloses the carrier having a degree of curvature in a relaxed condition (Col. 4, lines 39-40; Figure 4D).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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15. Claims 9, 10, 16, and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. (WO 00/69513) as applied to claims 7 and 15, and further in view of Dutcher et al. (US 5,143,090).

Regarding claims 9 and 16, Kuzma as applied to claims 7 and 15 is described above. Kuzma does not disclose a mesh material. However, Dutcher teaches using a porous polyester fiber (Col. 5, lines 29-31; Figure 5), which is considered equivalent to Applicant's mesh material, in order to enhance tissue ingrowth to firmly fix the lead to target tissue (Col. 6, lines 26-27). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the mesh material of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue.

Regarding claims 10 and 17, Kuzma does not disclose mesh material molded within the collar. However, Dutcher further teaches including the mesh material with the collar of the lead, in order to insure a secure connection of the electrodes (Col. 5, lines 29-32; Figures 5 and 6). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the molding the mesh material with the collar of Dutcher with the device of Kuzma for the purpose of insuring a secure connection of the electrodes.

16. Claims 12 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. (WO 00/69513) as applied to claims 1 and 15, and further in view of Kuzma (US 6,163,729).

Regarding claim 12 and 19, Kuzma '69513 does not disclose an indicator means on the collar. However, Kuzma '729 teaches the use of an indicator 203 provided on the collar (Figure 2), for the purpose of preventing the electrode from being inserted too deep (Col. 6, line 65-Col. 7, line 17). Therefore, it would have been obvious to one with ordinary skill in the art at the time the

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invention was made to include the indicator of Kuzma '729 with the device of Kuzma '69513, in order to prevent the electrode from being inserted too deep.

17. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (US 6,070,105) in view of Kuzma et al. (WO 00/69513).

Regarding claim 18, Kuzma '105 discloses the same invention substantially as claimed, including an elongate carrier 104 (Figure 1A) having a proximal end 108, distal end 106, and plurality of electrodes 102, and a carrier having a degree of curvature in a relaxed condition (Col. 4, lines 39-40; Figure 4D). Kuzma '105 does not disclose an anchoring means. However, Kuzma '69513 teaches using an anchoring means 16 (Figure 2), in order to prevent the electrode array from slipping out of the cochlea (Page 8, lines 21-22). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Kuzma '105 to include the anchoring means of Kuzma '69513 in order to prevent the electrode array from slipping out of the cochlea.

18. Claims 23 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. (WO 00/69513) as applied to claim 22, and further in view of Knudsen et al. (US 4,487,210).

Regarding claims 23 and 24, Kuzma does not disclose fabricating a fascia washer and placing it over the electrode. However, Knudsen discloses fabricating a fascia washer from tissues from the head (Col. 2, lines 3-5), which is considered equivalent to Applicant's temporalis fascia harvested from recipient, and packing it around the lead, which is considered equivalent to placing it over the electrode array, for the purpose of anchoring the leads in place. Knudsen does not disclose placing the fascia washer over the electrode prior to insertion into the cochlea. However, it would have

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been obvious to place the fascia washer on the electrode prior to insertion since such a modification would have involved a mere change in sequence. A change in sequence is generally recognized as being within the level of ordinary skill in the art. See *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959), *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the fabricating a fascia washer from temporalis fascia and placing it over the electrode array of Knudsen with the method of Kuzma, for the purpose of anchoring the electrode array in place.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Berrang (US 6,306,168) shows implanting an electrode into the cochlea.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eugene T. Wu whose telephone number is (571) 272-3109. The examiner can normally be reached on M-F: 9 AM - 5 PM EST.

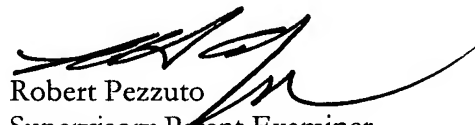
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ETW

01/30/2007



Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766